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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,616	11/12/2003	Jing Huang	3533.1	2187

22886 7590 04/24/2007

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EXAMINER
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AGRAWAL, RITESH

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,616	<b>Applicant(s)</b> HUANG ET AL.	
	<b>Examiner</b> Ritesh Agrawal	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-19,21-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-19,21,22 and 26-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' amendment and request for reconsideration in the communication filed on 1/29/07 are acknowledged and the amendments entered.

Claims 1-7, 9-19, 21-32, and 34 are currently pending.

Claims 1-7, 9-19, 21-22, and 26-32 are under consideration.

### ***Withdrawn Rejections***

2. The rejection of claims 1-7, 12-15, 17, 19-20, and 30-31 under 35 U.S.C. 103 (a) over the combination of Lindblad-Toh, Zhou, Draghici, and Kaminski is withdrawn in light of the amendments to the claims filed 1/29/07.

### ***Specification***

3. The specification is objected to because of the following:

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

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Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because the abstract is not drawn to the elected invention, namely, a method for determining DNA copy number.

Furthermore, whereas the claims are drawn to a method, the abstract does not provide any method steps. Additionally, the abstract provides speculative applications of the method. Correction is required. See MPEP § 608.01(b).

The above objection is reiterated from the Office action mailed 10/24/06.

Applicants' argument filed 1/29/07 has been fully considered but it is not persuasive.

Applicants' argue that they have amended the abstract in accordance with the examiner's suggestions (remarks, page 16, 1<sup>st</sup> paragraph). However, no amended abstract could be found.

Applicants' have provided amendments for a paragraph on page 81 of the specification (see remarks, page 4). However, the specification, as originally filed, only has 68 pages. It is therefore unclear as to which paragraph applicants' amendment refers.

This objection is newly applied, but necessitated by applicants' amendment.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7, 9-19, 21-22, and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the measurement, S, is the log of the arithmetic average of the intensities of at least two of the perfect match probes for the SNP" in step (e). As there are a plurality of perfect match probes for each of both a first and second allele of a SNP, it is unclear as to what probe intensities are averaged. Are the probes for the first allele, second allele, or both averaged together?

Claim 1 recites the limitation "the average mean of the normalized S values for SNP j in a plurality of reference samples" in step (i). There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to normalized S values for reference samples in the claim. Furthermore, since an average is a mean, it is an unclear what an average mean represents.

Claim 9 recites an equation using variables  $\phi$  and  $\sigma$ . As these variables are undefined, the limitations of the claim are unclear.

Claim 11 recites an equation using variables  $\phi$  and  $\sigma$ . As these variables are undefined, the limitations of the claim are unclear.

Claim 19 recites the limitation "the average mean of the normalized S values" in step (i). There is insufficient antecedent basis for this limitation in the claim. While there

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is a prior recitation of normalized mean S values, there is no prior recitation of an "average mean of the normalized S values." Furthermore, since average and mean are synonymous, it is unclear what an average mean represents.

Claim 19 recites the limitation "the normal copy number of the SNP" in the second to last line. There is insufficient antecedent basis for this limitation in the claim. There is no prior recitation of a "normal copy number" of a SNP in the claim. It is unclear if this is supposed to be the "known copy number" or if this with respect to some type of "normal" sample.

Claim 26 recites the limitation of an equation for obtaining a probability of homozygosity in line 7. The variables AA and BB are not defined. It is unclear if these are supposed to represent two allele types at a particular SNP.

Claim 26 recites the limitation of "the reference sample" in the second to last line. Since there are multiple reference samples, it is unclear as to which of these samples the limitation refers.

Claim 28 recites the limitation "the average mean of the normalized S values" in line 5. There is insufficient antecedent basis for this limitation in the claim. While there is a prior recitation of an average of normalized S values, there is no prior recitation of an average mean of normalized S values. Since the terms average and mean are synonymous, and there is no recitation of its calculation, it is unclear what an average mean represents.

Claim 28 recites an equation in line 2 for the calculation of a p-value. However, the claim does not define what the term  $\phi$  represents. The limitations of the claim are therefore unclear.

Claim 30 recites the limitation "computer code for inputting a plurality of perfect match intensity values ( $PM_i$ ) for a plurality of SNPs" in lines 2-3. It is unclear if a plurality of values is input for each of a plurality of SNPs, or if a plurality of intensity values is input because a plurality of SNPs are measured wherein each SNP can contribute any number of intensity values.

Claim 30 recites the limitation "calculating a log of the mean of the intensity value for each individual SNP in all reference samples" in lines 8-9. It is unclear what set of numbers the log of the mean is calculated over. First, since each SNP has multiple intensity values, it is unclear which of these values is used and, if a single value is used, how one calculates an average over a single number. Even if one assumes that a single value is used for each SNP from each sample and then averaged over all of the samples, it is unclear which intensity value is used. If one assumes that multiple intensity values are used for each SNP, it is unclear if all the values for each SNP are averaged for each sample and then log-transformed or if all of the intensity values for each SNP are averaged over all of the samples and then log transformed.

Claim 30 recites the limitation "calculating a log intensity difference between the log mean intensity of a SNP from an experimental sample and the log mean intensity of that SNP from reference samples" in lines 10-12. It is unclear if this calculation occurs separately between log mean intensities calculated for the experimental sample and

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each of the reference samples, or is there is a single calculation between the log mean intensity of the experimental sample and a log mean intensity calculated over all of the reference samples.

Claim 30 recites the limitation " the average mean of the normalized S values for SNP j in a plurality of reference samples" in lines 16-17. There is insufficient antecedent basis for this limitation in the claim. As there is no prior reference to normalized S values or average means taken thereof in the claim, the recited limitation is indefinite.

Claim 30 recites the limitation "the normal copy number" in line 21. There is insufficient antecedent basis for this limitation in the claim. As there is no prior recitation of the term in the claim, it is unclear if it represents the earlier recited "known copy number" or if it refers to a copy number derived from some normal sample.

Claim 32 recites an equation for calculating a p-value in line 2. The claim does not define the variable  $\phi$ , and therefore the claim is indefinite.

### ***Conclusion***

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

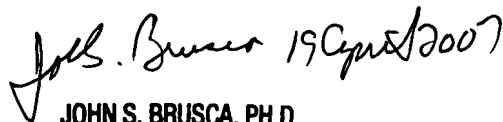


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal, PhD



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PRIMARY EXAMINER